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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/485,129	06/07/95	WALLACH D	WALLACH=5B

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EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	20

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/485,129	Applicant(s) Wallach et al.
	Examiner Ron Schwadron, Ph.D.	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Dec 7, 1998* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *11-14, 35-39, and 43-50* is/are pending in the application.

Of the above, claim(s) *14, 39, 45, and 50* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *11-13, 35-38, 43, 44, and 46-49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

15. Claims 11-13,35-38,43,44,46-49 are under consideration. Claims 34,40-42 have been cancelled. Claims 11,35,36,46-49 have been amended. Nonelected claim 50 has also been amended.

RESPONSE TO APPLICANTS ARGUMENTS

16. Regarding applicants comments on pages 4 and 5 of the amendment filed 12/7/98, in the event that the claims currently under consideration are found allowable, withdrawn claim 50 will be treated as per M.P.E.P. section 821.04 (July 1998).

17. Claims 11-13,46-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "including, at the N-terminal region thereof, the amino acid sequence: Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr" in claims 11 or 46. The specification and original claim 6 disclose that the aforementioned sequence was determined by "N-terminal sequence analysis" (eg. see page 23). This indicates that said sequence is in a particular area of the N-terminal region of the TBP-II molecule recited in the claim, as determined by N-terminal amino acid sequence analysis. The specification discloses that N-terminal amino acid sequence analysis revealed that said sequence was the beginning of the N-terminal of the sequenced molecule or found at two distinct positions in two other molecules determined by N-terminal amino acid sequence (see page 23). Thus, the specification discloses that the sequence recited in the claims is found at a particular location of the protein in which it occurs. The sequence as recited in the claims under consideration encompasses molecules wherein said sequence is found anywhere in the N-terminal region. Thus, said language would encompass a nucleic acid wherein the sequence recited in the claims was found in a variety of different

positions as long as it was in the "N-terminal region" (eg. it could occur at five amino acids from the N-terminal or fifteen or twenty amino acids from the N-terminal, etc). There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed inventions constitute new matter). Regarding applicants comments about the use of the term "N-terminal region" as recited in paragraph 18 of the previous Office Action, said rejection does not state that use of the phrase "N-terminal region" would not constitute new matter. Said phrase was not recited in the claim addressed in the rejection recited in paragraph 18 of the previous Office Action. In fact, said rejection clearly states that "A preferred substitution uses the language in original claim 6 with regards to the location of the sequence recited in the claim". Applicants arguments have been considered and deemed not persuasive.

18. Claims 35,43,44 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification as originally filed for the claimed molecules. The specification discloses that the features of the TBP-II molecule recited in claim 35 are found in a molecule of 30kd. However, there is no disclosure in the specification of the existence of a TBP-II molecule recited in claim 35 other than one wherein the molecular weight is 30kd. The scope of the claimed molecule exceeds the scope of the disclosure of the specification as originally filed. There is no written description of such a molecule in the specification as originally filed (eg. it constitutes new matter).

Regarding applicants comments in the instant amendment, applicant has not revealed where in the specification that the claimed invention finds support. The specification clearly states on page 23 that the sequences disclosed in said page were found upon N-terminal sequence analysis of the 30 kDa band of purified protein. There is no disclosure in the specification of the existence of a TBP-II molecule recited in claim 35 other than one wherein the molecular weight is 30kd. Regarding applicants comments about what claim 35 is drawn to, said claim while drawn to a nucleic acid recites that said nucleic acid encodes the particular protein recited in the claim. There is no support in the specification as originally filed for the claimed invention. Regarding applicants

comments about the size of the molecule encoding by the claimed nucleic acid, there is no disclosure in the specification of the existence of a TBP-II molecule recited in claim 35 other than one wherein the molecular weight is 30kd.

19. Claims 11-13,35-38,43,44,46-49 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed DNAs and molecules containing said DNAs.

The instant claims encompass an isolated DNA molecule or vectors or host cells which contain said DNA wherein said DNA encodes a protein consisting of naturally occurring TBP-II. There is no disclosure in the specification of an intact DNA sequence which encodes said molecule. There is no disclosure in the specification of any DNA sequence which encodes the claimed DNA. The claimed molecule recites physical features of a TBP-II protein and the amino acid sequences of a 10-13 amino acid sequence of the N terminal of a molecule that contains at least 250 amino acids. There is no disclosure in the specification of any DNA sequence which encodes the claimed molecule. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin

from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has not provided even a single DNA sequence which encodes the claimed DNA . The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments in the instant amendment about University of California v. Eli Lilly, there is still no disclosure in the specification of any nucleic acid encoding the scope of the claimed invention (eg. a nucleic acid encoding TBP-II). There is also no disclosure in the specification of the amino acid sequence of intact TBP-II. While the specification discloses N-terminal amino acid sequence data indicating a possible partial amino acid sequence of 31 amino acids of TBP-II, said peptide contains at least 250 amino acids, wherein the identity of the vast majority of said amino acids has not been disclosed in the specification. In University of California v. Eli Lilly, the court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has not provided even a single DNA sequence which encodes the claimed DNA. The Federal Circuit has

held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Regarding applicants comments that the intact amino acid sequence of TBP-II could be obtained using the methods disclosed in the specification, this is not the issue under consideration. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Clearly, in the instant application, the inventor is unable to envision the detailed constitution of a nucleic acid so as to distinguish it from other materials because the sequence of the claimed nucleic acid was not known to the inventors at the time of the filing date of the instant application. Regarding applicants comments about the TBP-II protein, none of the claims of the instant invention are drawn to TBP-II protein. The claims under consideration are drawn to nucleic acids. The possession of an isolated protein in itself provides no written description of the identity of the nucleic acid encoding said protein in the absence of the complete amino acid sequence of said protein. Applicants response recites "Once the complete amino acid sequence is known, all contiguous DNA sequences which encode such a protein are known in view of the known rules of the genetic code."(page 11). However, the complete amino acid sequence of TBP-II is not disclosed in the instant application. The instant application merely recites methods that could be potentially used to elucidate the nature of said sequence. In the absence of the disclosure of the claimed nucleic acid in the specification or the complete amino acid sequence of TBP-II there is no written description of the scope of the claimed invention. Regarding applicants comments that University of California v. Eli Lilly only applies to "genes"

per se, this not stated in University of California v. Eli Lilly. In fact, in University of California v. Eli Lilly the court clearly states that :

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

In the instant application, applicants has provided a plan and potential method for isolating the claimed nucleic acids, but have provided no written description of said nucleic acids.

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

21. Claims 11-13,35-38,43,44,46-49 remain rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. (US Patent 5,395,760).

Smith et al. teach the claimed inventions (see Figure 2a and claims). This rejection can be overcome by the submission of English language copies of the foreign priority documents, assuming the claimed inventions are disclosed in said foreign priority documents.

Regarding the priority documents and applicants comments in the instant amendment, certified copies of said documents were not filed with the instant application. An examination of the file of parent application 07/930443 also did not reveal the presence of the certified foreign priority documents. This issue could be addressed by submission of copies of the certified foreign priority documents. In addition, for the same reasons that the claims under consideration were rejected as containing new matter in this Office Action, said claims do not have priority to the foreign priority documents as cited in the instant application.

22. No claim is allowed.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
February 25, 1999